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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,884	07/10/2003	Brian M. Hatcher	5853-428	2636

7590 06/13/2007

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,884	HATCHER ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group II in the reply filed on 8/16/06 is acknowledged. Applicant however provides no substantive arguments in the traversal. Since no arguments are presented the requirement is held final. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11,13-17,21,23,24,26-30,32,34,36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce et al (USPN 6,294,041 hereafter '041). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

4. The '041 patent teaches an osteoimplant comprising calcium phosphate, active agents and other common ingredients (abstract). The implant comprises bioabsorbable polymers and excipients such as starches, polymethyl methacrylates, polyethylene and other common polymers (col. 4, lin. 25-40). The implant further comprises bioactive compounds such as antiviral agents,

and biological compounds such as stem cells and collagen, along with various growth factors (col. 4, lin. 60-col. 5, lin. 15). The implant is applied to an injured or defective area in order to repair the effected area (col. 5, lin. 65-col. 6, lin. 25). The collagen is surface bonded to the implant (col. 6, lin. 26-35). The composition is present in various forms including fibers (example 1). Theses disclosures render the claims anticipated.

5. Claims 11-14,26,27,28,30,31, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (USPN 6,027,742 hereafter '742). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

6. The '742 patent teaches a bioresorbable ceramic composite comprising calcium phosphate and other materials (abstract). The composite comprises collagen, demineralized bone and other natural material l (col. 9, lin. 45-48) as well as polymers such as polyesters of carboxylic acids (col. 9, lin. 50-55). The further includes harvested cells that are seeded into the implant and proliferate at the implantation site (col. 12, lin. 10-22). The composites are formed by well-known methods including mixing, blending and alloying (col. 13, lin. 62-65). The particles produced range in size from 25-200 microns (example 6). These disclosures render the claims anticipated.

7. Claims 11,12,17-19,30,33,36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Marotta et al (USPN 5,990,380 hereafter '380). The claims are drawn to a

composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The composite comprises fibers that are equally spaced. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

8. The '380 patent teaches a bioglass implant comprising calcium and phosphate molecules in a composite with others compounds (abstract, table 1). The particles are below 100 microns (col. 6, lin. 5-12) and are present in fibers that are spaced from 20-200 microns apart (claims, examples). The composite is formed at room temperature by mixing the components (examples). These disclosures render the claims anticipated.

9. Claims 11-13,21,22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ducheyne et al (USPN 5,676,720 hereafter '720). The claims are drawn to a composite material comprising a bioglass and biologically active agents. The composite is delivered for sustained release profile.

10. The '720 patent teaches a porous bioglass composite comprising calcium and phosphate molecules (abstract) and other compounds (claims). The composite encapsulates an active agent such as a cell on its surface and is implanted allowing for sustained interaction with the defective implant area (col. 8, lin. 44-65). These disclosures render the claims anticipated.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 11,20, and 36-38 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Niederauer et al (USPN 6,344,496 hereafter '496). The claims are drawn to a bioglass composite comprising a calcium and phosphate molecule along with other common excipients. The composite has a porosity of at least 50%. The claims further recite a method of making the composite where the temperature is below 200 degrees Celsius and the composition is sprayed or extruded.

12. The '496 patent teaches a bioglass composite comprises a calcium and phosphate bioglass compound (col. 4, lin. 19-38). The composite further comprises polymers known in the art such as polyglycolide and glycolide/lactide copolymers (col. 5, lin. 62-col. 6, lin. 18). The composite is used as an implantable device (col. 6, lin. 49-59). The porosity of the composite is between 60-90 % (col. 8, lin. 5-15). The composite is formed at room temperature and is spray-dried (examples). These disclosures render the claims anticipated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER